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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,618	12/21/2001	Bernhard Clasbrummel	P01,0578	4762

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EXAMINER
ORTIZ RODRIGUEZ, CARLOS R

ART UNIT	PAPER NUMBER
2125	8

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,618	CLASBRUMMEL ET AL.	
	Examiner	Art Unit	
	Carlos Ortiz-Rodriguez	2125	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2002* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 and 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over White U.S Patent No. 4,436,684 in view of Kienzle, III et al. U.S. Patent No. 6,285,902.

Regarding claim 1, White et al. discloses a method for preparing an anatomical implant (see col. 2 lines 13-14 and col. 1 lines 7-9), comprising the steps of: intra-operatively generating a three-dimensional dataset (see col. 1 lines 10-12) of body tissue (see col. 1 lines 46-50 also see col. 24 lines 44-46) of a subject exhibiting a fault to be corrected by an implant (see col. 1 lines 59-65) from a series of two dimensional projections of the body tissue obtained from respectively different projection directions(see col 2 lines 63-68 and col 24-28); and intra-operatively preparing said implant adapted for introduction into said subject from said three-dimensional dataset (see col 2 lines 14-22).

But, White et al. fails to clearly disclose a C-arm. However, Kienzle, III et al. discloses a movable C-arm x-ray apparatus, but moving an x-ray source and a radiation receiver on a C-arm around said subject (see fig 1 and fig 7 also see col 8 lines 14-23).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and modifying it with the invention disclosed by Kienzle, III et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

One of ordinary skill in the art would have been motivated to do this modification because C-arms are frequently utilized in the art, especially for CT (computed tomography) scan as suggested by Kienzle, III et al. CT scan is the process of using digital processing to generate a three-dimensional image of the internal of an object from a series of two-dimensional x-ray images. The individual x-ray axial slice images are taken using a x-ray tube that rotates around the object taking many scans as the object.

Regarding claim 2, White in combination with Kienzle, III et al. disclose all the limitations based on claim 1. White further discloses a method comprising acquiring a three-dimensional dataset which represents a bone structure of said subject(see col 9 lines 63-65 and col 10 lines 50-54 and also see fig.10).

Regarding claim 3, White in combination with Kienzle, III et al. disclose all the limitations based on claim 1. White further discloses a method comprising intra-operatively preparing said implant with an automated device which is supplied with said three-dimensional dataset (see col 2 lines 14-22 also see fig 8a).

Regarding claim 4, White discloses an apparatus for preparing an anatomical implant (see col 2 lines 13-14 and col 1 lines 7-9), an apparatus intra-operatively generating a three-dimensional dataset (see col 1 lines 10-12) of body tissue (see col 1 lines 46-50 also see col 24 lines 44-46) of a subject exhibiting a fault, to be corrected with an implant (see col 1 lines 59-65), by obtaining a series of two-dimensional projections of the body tissue from respectively different projection directions(see col 2 lines 63-68 and col 24-28) by moving a x-ray source and said radiation detector thereon, around the body tissue(see col 8 lines 53-58); and an implant-producing device which intra-operatively produces said implant from said three-dimensional dataset(see col 2 lines 14-22 also see fig 8a).

But, White fails to clearly disclose a C-arm. However, Kienzle, III et al discloses a C-arm C-arm comprising a x-ray apparatus having an x-ray source and a radiation receiver mounted thereon (see Kienzle fig 1 and fig 7 also see col 8 lines 14-23), said C-arm x-ray apparatus intra-operatively generating a three-dimensional dataset (see col 1 lines 10-12).

Therefore at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the above invention suggested by White et al. and modifying it with the invention disclosed by Kienzle, III et al. The results of this modification would lead to a method and apparatus for preparing an anatomical implant.

One of ordinary skill in the art would have been motivated to do this modification because C-arms are frequently utilized in the art, especially for CT (computed tomography) scan as suggested by Kienzle, III et al. CT scan is the process of using digital processing to generate a three-dimensional image of the internal of an object from a series of two-dimensional x-ray

images. The individual x-ray axial slice images are taken using a x-ray tube that rotates around the object taking many scans as the object.

Regarding claim 5, White in combination with Kienzle, III et al. disclose all the limitations based on claim 4. White further discloses an apparatus wherein said dataset represents a bone structure, and wherein said implant is adapted to replace said bone structure (see col.3 lines 24-31 also see col.24 lines 40-43).

Regarding claim 6, White in combination with Kienzle, III et al. disclose all the limitations based on claim 4. White further discloses an apparatus wherein said implant-preparing device is an automated device which is supplied with said three-dimensional dataset and automatically prepares said implant therefrom (see col 2 lines 14-22 col. 9 lines 29-40 and also see fig 8a).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to further show the state of the art with respect to method and apparatus for preparing an anatomical implant:

a. U.S. Pat. No. 5,452,407 to Crook et al., which discloses method for representing a patient's treatment site as data for use with CAD or CAM device.

b. U.S. Pat. No. 5,487,012 to Topholm et al., which discloses a method of preparing an otoplasty or adaptive earpiece individually matched to the shape of an auditory canal.

c. U.S. Pat. No. 5,725,376 to Poirier, which discloses methods for manufacturing a dental implant drill guide and dental implant superstructure.

The following publications are cited to further show the state of the art with respect to method and apparatus for preparing an anatomical implant:

d. U.S. Pub. No. 2002/0071523 to Busse et al., which discloses X-ray detector provided with integrated cooling.

e. U.S. Pub. No. 2002/0077541 to Kienzle,III which discloses computer assisted intramedullary rod surgery system with enhanced features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos Ortiz-Rodriguez whose telephone number is (703) 305-8009. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Leo P. Picard can be reached on (703) 308-0538. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-6606.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-4750.

Carlos Ortiz-Rodriguez
Patent Examiner
Art Unit 2125

cror

April 9, 2003

LEO PICARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100